

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wieker

### REMARKS

Claims 1-22 and 24-30 are pending in the application and are presented for the Examiner's review and consideration. Claims 1, 13, 16, 17, 21, and 29 have been amended and claim 23 has been cancelled. Applicants believe that the claim amendments, cancellation, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that that they do not limit the range of any permissible equivalents.

#### In the Drawings

The drawings were objected to under 37 CFR 1.83(a). Specifically, the Examiner stated the articulately mounted second cuff (claim 8); the articulately mounted hand pad (claim 17); and the locking assembly (claim 23) must be shown or the features cancelled from the claims. For the reasons set forth below, Applicants respectfully submit that the drawings show every feature of the invention specified in the claims.

As an initial matter, claim 23 has been cancelled thereby rendering the objection to the drawings in view of this claim moot.

The present invention discloses, referring to FIGS. 14 and 15, an embodiment in which the hand pad 38 articulates with respect to the second arm member 14. (§[0070]). The circular base member 40 supports a circular base plate 42. (Id.) A circular cover 44 extends upwardly from the circular base member 40 and has a portion 46 extending radially inwardly toward a vertical axis 48 to define a slide chamber 50. (Id.)

A hand pad support slider 52 is received in the slide chamber 50. The support slider 52 has an upper portion 54 to which the hand pad 38 is attached. (§[0071]). Thus, the hand pad 38 is slidable relative to the circular base member 40 in any direction for a limited extent. (§[0072]). As indicated by the arrow 68, the hand pad 38 is slidable fore and aft within the extent of travel allowed by the support slider 52 within the slide chamber 50. As indicated by the

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wiekert

arrow 70, the hand pad 38 is slidable laterally within the extent of travel allowed by the support slider 52 within the slide chamber 50. (Id.)

As such, FIGS. 14 and 15 show a second arm member including a support slider 52 received in the slide chamber 50, where a hand pad 38 is attached to an upper portion 54 of the support slider 52. The movement of the support slider 52 in the slide chamber 50 allows the hand pad 38 to move in any direction with respect to the second arm 14. Accordingly, FIGS. 14 and 15 shows the features of the invention as specified in claims 8 and 17

In light of the foregoing, Applicants request reconsideration and withdrawal of the objection to the drawings.

#### In the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The Examiner stated that the specification lacks antecedent basis for the subject matter of claims 8 and 17. As set forth above, Applicants respectfully submit that both the drawings and the specification support the subject matter of claims 8 and 17. Accordingly, Applicants request reconsideration and withdrawal of the objection to the specification.

The abstract was also objected to. In response, Applicants have amended the abstract.

#### Claim Objections

Claims 13 and 21 were objected to due to informalities. Applicants have amended these claims to address the objections.

#### 35 U.S.C. § 112 Rejections

Claims 8 and 17 were rejected under 35 U.S.C 112, first paragraph, as failing to comply with the enablement requirement.

As noted above, FIGS. 14 and 15 show a second arm member including a support slider 52 received in the slide chamber 50, where a hand pad 38 is attached to an upper portion 54 of

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wicker

the support slider 52. The movement of the support slider 52 in the slide chamber 50 allows the hand pad 38 to move in any direction with respect to the second arm 14. As such, the specification describes the subject matter of the claims as to enable one skilled in the art to make and use the invention.

Applicants note that hand pad 38 is articulately mounted to the second arm 14, allowing motion of the hand pad 40 to move in any direction with respect to the second arm 14. Furthermore, because the cuffs 32 and 34 are clamped onto the first and second body portions as described above, the outward pivoting movement of the first and second arm members 12 and 14 and the cuffs 32 and 34 causes the joint to be extended as desired. (§[0046]). However, this extension of the joint can place strong distractive forces on the soft tissues around the joint. (Id.)

The sliding movement of the cuffs 32 and 34, inwardly along the first and second arm members 12 and 14, helps to limit these distractive forces by counteracting the outward movement of the first and second arm members 12 and 14.

Because the cuffs 32 and 34 are clamped onto the first and second body portions, the inward pivoting movement of the first and second arm members 12 and 14 and the cuffs 32 and 34 causes the joint to be flexed as desired. (§[0048]). However, this flexion of the joint can place strong compressive forces on the soft tissues around the joint. (Id). The sliding movement of the cuffs 32 and 34, outwardly along the first and second arm members 12 and 14, helps to limit these compressive forces by counteracting the inward movement of the first and second arm members 12 and 14. (Id).

Additionally, when a joint is in flexion or extension it can exhibit a rotational motion, placing a torque on the joint. The articulation of the cuff/hand pad helps to limit these torques by counteracting the rotation of the joint.

Accordingly, Applicants submit that a cuff/hand pad articulately mounted to the second arm is not contrary to the desired function of the cuff/hand pad.

In light of the foregoing, Applicants request reconsideration and withdrawal of the section 112 rejections.

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wicker

35 U.S.C. § 102(b) Bonutti et al.

Claims 1-8, 18-21, and 24-27 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,113,562 to Bonutti et al. ("Bonutti"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are not taught or suggested by Bonutti.

Bonutti discloses an orthosis for rotating the humerus with respect to the shoulder. The orthosis includes a main drive gear affixed to the lower cuff arm, where the patient's elbow extends through an opening in the main gear. The main gear is operated to rotate the humerus about its axis relative to the shoulder. As shown in the Figures, the operative connection between the main gear and the upper cuff arm is offset from the axis of rotation of the humerus, such that a plane defined by the main gear as it is rotated through the upper cuff arm does not include the shoulder. Additionally, Bonutti does not disclose that the main gear travels along an arcuate path through the upper arm section member when the lower arm section is rotated from a first position to a second position about the axis of the humerus, wherein the arcuate path and the shoulder lie in a plane substantially orthogonal to an axis of rotation of the humerus.

In contrast, the present invention relates to an adjustable orthosis which can be used for stretching tissue such as ligaments, tendons or muscles around a joint during flexion or extension of the joint. (¶[0001]). The orthosis 10 includes a first arm member 12 attachable to the first body portion and a second arm member 14 attachable to the second body portion, wherein a joint axis of rotation 16 is interposed between and offset from the first and second arm members 12 and 14. (¶[0025]).

The first arm member 12 of the orthosis 10 includes a first extension member 18, which extends at angle  $\alpha$  from the first arm member 12. (¶[0026]). The second arm member 14 of the orthosis 10 includes a second extension member 20 extending therefrom and having an arcuate shape. (Id.) The first and second extension members 18 and 20 are operatively connected at point "P," such that in operation the second extension member 20 travels along an arcuate path about and substantially through point "P." (Id.) The orthosis 10 of the present invention is

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wieker

shown having an angle  $\alpha$  such that the operative connection, at point "P," of the first and second extensions 18 and 20 is located in a plane "A" passing through the joint axis 16, wherein plane "A" is substantially orthogonal to a longitudinal axis of the first arm member 12. ([0028]).

As such, the present invention discloses an orthosis having first and second arm members operably connected at a point "P." The first and second arm members each include extensions which are located in plane "A" which passes through the joint axis. The plane "A" is orthogonal to a longitudinal axis of the first arm member. Similarly as shown in the Figure, the plane "A" is also orthogonal to joint axis of rotation.

Claim 1 recites, *inter alia*, an orthosis for stretching tissue around a joint of a patient between first and second relatively pivotable body portions. The orthosis includes a first arm member affixable to the first body portion and having a first extension member extending therefrom. A second arm member is affixable to the second body portion and includes a second extension member having an arcuate shape extending therefrom. The second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member, wherein the arcuate path and the joint lie in a plane substantially orthogonal to an axis of rotation of the joint.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Bonutti. As claims 2-8, 18-21, and 24-27 depend from claim 1, and necessarily include all the elements of the base claim, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

35 U.S.C. § 102(b) Hotchkiss et al.

Claims 1-3, 5-6, 18-22, 24, and 26 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,376,091 to Hotchkiss et al. ("Hotchkiss"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are not taught or suggested by Hotchkiss.

Hotchkiss discloses a device having a pair of hinges aligned with the axis of the elbow

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wiekert

and located on both the medial and lateral side of the elbow joint. Each of the hinges can include a fitted plates adapted to rotate relative to arcuate members. The rotating plates may indirectly be mounted to the arcuate members through radially-extending arms. Accordingly, the fitted plates and arcuate members rotate in parallel planes on opposite sides of the elbow joint.

In contrast and as noted above, the orthosis of the present invention includes a first arm member affixable to the first body portion and having a first extension member extending therefrom. A second arm member affixable to the second body portion and including a second extension member having an arcuate shape extending therefrom is additionally included. The second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member. The arcuate path and the joint lie in a plane substantially orthogonal to an axis of rotation of the joint.

Claim 1 recites, *inter alia*, an orthosis for stretching tissue around a joint of a patient between first and second relatively pivotable body portions. The orthosis includes a first arm member affixable to the first body portion and having a first extension member extending therefrom. A second arm member is affixable to the second body portion and includes a second extension member having an arcuate shape extending therefrom. The second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the second arm member is moved from a first position to a second position relative to the first arm member, wherein the arcuate path and the joint lie in a plane substantially orthogonal to an axis of rotation of the joint.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Hotchkiss. As claims 2, 3, 5, 6, 18-22, 24, and 26 depend from claim 1, and necessarily include all the elements of the base claim, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wiekcr

35 U.S.C. § 102(b) Bonutti et al.

Claims 1-3, 5, 6, 8-15, 18-22, and 24-28 were rejected as anticipated by U.S. Patent No. 5,848,979 to Bonutti et al. ("Bonutti"). For the reasons set forth below, Applicants respectfully submit that the rejected claims are not taught or suggested by Bonutti.

Bonutti discloses an orthosis having upper and lower cuff arms which are pivotally interconnected. The lower cuff arm includes a lower cuff, where the drive mechanism connects the lower cuff to the lower cuff arm. The drive assembly includes a main gear which is connected to the lower cuff. In operation, the lower cuff and main gear are rotated with respect to the lower cuff arm. Bonutti does not disclose that the upper cuff arm includes a first extension member extending therefrom and that the lower cuff arm includes a second extension member having an arcuate shape extending therefrom, where the second extension member is operatively connected to the first extension member and travels along an arcuate path through the first extension member when the lower cuff arm member is moved from a first position to a second position relative to the upper cuff arm member.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Bonutti. As claims 2, 3, 5, 6, 8-15, 18-22, and 24-28 depend from claim 1 and necessarily include all the elements of this base claim, Applicants respectfully submit that these dependent claims are also patentable at least for the same reasons.

35 U.S.C. § 103(a)

Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonutti '562 in view of Hotchkiss. For the reasons set forth below, Applicants respectfully submit that the rejected claim is patentable over Bonutti in view of Hotchkiss.

As noted above claim 1 is submitted to be patentable over Bonutti '562. The inclusion of Hotchkiss fails to change this. As claim 22 depends from claim 1 and necessarily includes all the elements of this base claim, Applicants respectfully submit that this dependent claim is also patentable at least for the same reasons.

Applicant: Bonutti et al.  
Application No.: 10/795,892  
Examiner: A. Wieker

### Allowable Claims

The Examiner stated that claims 16 and 29-30 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form,

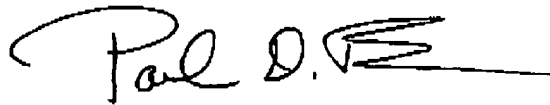
Applicants note that claim 30 was initially written in independent form. Additionally, Applicants have rewritten claims 16 and 29 as required by the Examiner.

### Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$100 for an additional independent claim and a (2 month) Extension of Time fee of \$ 225 are believed to be due and a Fee Transmittal Sheet with payment by credit card is submitted concurrently herewith. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 781-A04-025).

Respectfully submitted,



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